ATTORNEY'S DOCKET NO.: B0410/7269D2

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Richard A. Gambale et al.

Serial No.:

Not Yet Assigned

Filed:

Herewith

For:

VASCULAR INDUCING IMPLANTS

Examiner:

Sharon E. Kennedy

Art Unit:

3762

Express Mail mailing label number: \_\_

EV340040301US

Date of Deposit: January 29, 2004

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MAIL STOP PATENT APPLICATION

Commissioner for Patents

P. O. Box 1450

Alexandria, VA 22313-1450

# STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 C.F.R. §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the applicants request consideration of this information disclosure statement.

# Compliance with 37 C.F.R. §1.97

This information disclosure statement is being filed with the application. No fee or certification is required.

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## Compliance with 37 C.F.R. §1.98(d)

This application is a divisional of application Serial No. 09/774,319 filed January 31, 2001; which is a divisional of Serial No. 09/164,173 filed September 30, 1998. Information listed on the attached PTO 1449 form and marked with an asterisk (\*) indicates information that was also cited in the parent application in compliance with 37 C.F.R. §1.98(a)-(c). Copies of these references have not been resubmitted with this filing.

### **Information Cited**

The applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the relative importance of the references.

# Explanation of Non-English Language References and Remarks Concerning Other Information Cited

The following is a concise explanation of the relevance of each non-English language reference listed on the attached form PTO-1449 (modified):

**DE 19703482, and DE 29619029U1** are German language documents. An English language Derwent abstract for each was provided with the parent application.

FR 1,514,319 is a French language documents. Due to the age of the document, an English language abstract was not available from the Derwent World Patent Index database. For FR 2,725,615, an English language Derwent abstract for each was provided with the parent application.

RU 2026640 C1 and RU 2063179 C1 are Russian language documents. An English language Derwent abstract for each was provided with the parent application.

#### Remarks

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

 The examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

- The enclosed form PTO-1449 be signed by the examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
- The citations for the information be printed on any patent, which issues from this application.

By submitting this information disclosure statement, the applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this information disclosure statement, the applicant makes no representation that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this information disclosure statement, the applicant makes no representation that the information cited in the statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is understood by applicant that the foregoing information will be considered and, to the extent deemed appropriate by the examiner, will be reflected in the examiner's communication.

Respectfully submitted,

ohn F. Perullo Reg. No. 39,498

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Docket No.: B0410/7269D2 Date: January 29, 2004

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Form PTO-1449 INFORMATION	Docket No.: B0410/7269D2	Serial No. Not Yet Known	
DISCLOSURE STATEMENT	Applicant: Richard A. Gambale		
	Filed: Herewith	Group: 3762	

_				Patent Documents			· · · · · · · · · · · · · · · · · · ·
Ex.	<del></del>	Doc. No.	Date	Name	Class	Subcl.	Filed
	*	575,451	01/1897	Yost			
	*	3,991,750	11/1976	Vickery	ļ		
	*	3,995,617	12/1976	Watkins et al.			
	*	4,184,469	04/1979	Geyer			
	*	4,307,722	12/1981	Evans et al.	<u> </u>		
	*	4,503,569	03/1985	Dotter			
	*	4,546,499	10/1985	Possis			
	*	4,562,597	01/1986	Possis et al.			
	*	4,580,568	04/1986	Gianturco			
	*	4,582,181	04/1986	Samson			
	*	4,641,653	02/1987	Rockey			
	*	4,649,922	03/1987	Wiktor			
	*	4,655,771	04/1987	Wallsten			
	*	4,658,817	04/1987	Hardy et al.			
	*	4,665,918	05/1987	Garza et al.			
	*	4,681,110	07/1987	Wiktor			
	*	4,733,665	03/1988	Palmaz			
	*	4,768,507	09/1988	Fischell et al.			
	*	4,774,949	10/1988	Fogarty			
**	*	4,813,925	03/1989	Anderson, Jr. et al.		-	<del></del>
	*	4,861,330	08/1989	Voss		<b>†</b>	
	*	4,889,137	12/1989	Kolobow			
	*	4,904,264	02/1990	Scheunemann			
	*	4,917,666	04/1990	Solar et al.		<del></del>	<del>                                     </del>
	*	4,920,980	05/1990	Jackowski		<del>                                     </del>	
	*	4,950,227	08/1990	Savin et al.		<del> </del>	<del> </del>
	*	4,994,071	02/1991	MacGregor		<del></del>	<del> </del>
	*	4,995,857	02/1991	Arnold			
	*	4,997,431	03/1991	Isner et al.	<del> </del>	<del> </del>	
	*	5,040,543	08/1991	Badera et al.	<del> </del>	+	
	*	5,042,486	08/1991	Pfeiler et al.		-	
	*	5,047,028	09/1991	Qian			
	*	5,049,138	09/1991	Chevalier et al.	<del></del>		
<del></del>	*	5,056,517	10/1991	Fenici		<del> </del>	<del> </del>
	*	5,087,243	02/1992	Avitall	<del> </del>	+	
	*	5,098,374	03/1992	Othel-Jacobsen et al.		<del>                                     </del>	+
	*	5,114,414	05/1992	Buchbinder		<del> </del>	
	*			<del></del>	<del> </del>	<del> </del>	<del> </del>
	*	5,158,548	10/1992	Lau et al.	+	<del> </del>	<del> </del>
	*	5,167,614	12/1992	Tessman et al.			
		5,176,626	01/1993	Soehendra	<u> </u>		1

			U.S. F	Patent Documents			
Ex.		Doc. No.	Date	Name	Class	Subcl.	Filed
	*	5,180,366	01/1993	Woods			
	*	5,190,058	03/1993	Jones et al.			
	*	5,203,456	04/1993	Amadore			
	*	5,256,146	10/1993	Ensminger et al.			1
	*	5,266,073	11/1993	Wall			
	*	5,287,861	02/1994	Wilk			
	*	5,290,295	03/1994	Querals et al.			
	*	5,312,456	05/1994	Reed et al.			
	*	5,324,325	06/1994	Moaddeb			
	*	5,366,493	11/1994	Scheiner et al.			
	*	5,372,600	12/1994	Beyar et al.		Ĭ	
	*	5,380,316	01/1995	Alta et al.			
	*	5,389,096	02/1995	Alta et al.			
	*	5,391,199	02/1995	Ben-Haim			
	*	5,409,004	04/1995	Sloan			
	*	5,409,019	04/1995	Wilk			
	*	5,423,885	06/1995	Williams			
	*	5,425,757	06/1995	Tiefenbrun et al.			
	*	5,429,144	07/1995	Wilk			
	*	5,441,516	08/1995	Wang et al.			
	*	5,452,733	09/1995	Sterman			
	*	5,453,090	09/1995	Martinez et al.			
	*	5,458,615	10/1995	Klemm			
	*	5,464,404	11/1995	Abela et al.			·
	*	5,464,650	11/1995	Berg et al.			
	*	5,466,242	11/1995	Mori			
	*	5,476,505	12/1995	Limon			
	*	5,480,422	01/1996	Ben-Halm		<u> </u>	<del></del>
he	*	5,482,261	01/1996	Ortega			
	*	5,487,739	01/1996	Aebischer et al.		<del> </del>	
	*	5,514,176	05/1996	Bosley, Jr. et al.			
· · · · · · · · · · · · · · · · · · ·	*	5,551,427	09/1996	Altman			
-	*	5,551,954	09/1996	Buscemi et al.			<del></del>
	*	5,562,619	10/1996	Mirarchi et al.			
	*	5,562,922	10/1996	Lambert			
	*	5,569,272	10/1996	Reed et al.			
	*	5,571,168	11/1996	Toro			-
<del></del>	*	5,593,412	01/1997	Martinez et al.			1
	*	5,593,434	01/1997	Williams			
	*	5,602,301	02/1997	Field			
	*	5,614,206	03/1997	Randolf et al.			
	*	5,628,783	05/1997	Quiachon et al.		1	1
<u> </u>	*	5,643,308	07/1997	Markman			
	*	5,653,756	08/1997	Clarke et al.	-	<del>                                     </del>	
	*	5,655,548	08/1997	Nelson			†
	*	5,662,124	09/1997	Wilk	<del></del>	1	+
	+	5,669,924	09/1997	Shaknovich		+	<del> </del>

	•		U.S. F	Patent Documents			
Ex.		Doc. No.	Date	Name	Class	Subcl.	Filed
	*	5,676,850	10/1997	Reed et al.			
	*	5,690,643	11/1997	Wijay			<u> </u>
	*	5,692,737	12/1997	Perlsweig			
	*	5,735,897	04/1998	Buirge			
	*	5,741,330	04/1998	Brauker et al.			
	*	5,744,515	04/1998	Clapper			
	*	5,755,682	05/1998	Knudson et al.			
	*	5,756,127	05/1998	Grisoni et al.			
•	*	5,762,600	06/1998	Bruchman et al.			
	*	5,769,843	06/1998	Abela et al.			
	*	5,782,823	07/1998	Mueller			
	*	5,785,702	07/1998	Murphy et al.			
	*	5,792,453	08/1998	Hammond et al.			
	*	5,797,870	08/1998	March et al.			
	*	5,807,384	09/1998	Mueller			
	*	5,810,836	09/1998	Hussein			
	*	5,824,049	10/1998	Ragheb et al.			
	*	5,824,071	10/1998	Nelson et al.			
	*	5,830,502	11/1998	Dong et al.			<del>                                     </del>
	*	5,840,059	11/1998	March et al.			1
	*	5,851,228	12/1998	Pinheiro			
	*	5,861,032	01/1999	Subramaniam			
	*	5,879,383	03/1999	Bruchman et al.			
	*	5,893,869	04/1999	Barnhart et al.			
	*	5,899,915	05/1999	Saadat			<u> </u>
	*	5,971,993	10/1999	Hussein			
	*	5,980,514	11/1999	Kupiecki et al.			
	*	5,980,548	11/1999	Evans et al.			
	*	6,033,434	03/2000	Borghi			
	*	6,045,565	04/2000	Ellis et al.			
	*	6,053,924	04/2000	Hussein			1
	*	6,086,611	07/2000	Duffy et al.			
****	*	6,099,560	08/2000	Penn et al.			
	*	6,263,880	07/2001	Parker et al.			
***	*	6,197,049	03/2001	Shaolian et al.			
	*	6,197,324	03/2001	Crittenden			
	*	6,248,112	06/2001	Gambale et al.		1	
	*	6,251,418	06/2001	Ahern et al.			<u> </u>
	*	6,277,082	08/2001	Gambale			
	*	6,395,022	05/2002	Piplani et al.			
<del></del>	*	6,432,126	08/2002	Gambale et al.			
	*	6,447,522	09/2002	Gambale et al.			

	U.S. PATENT APPLICATION DOCUMENTS					
Ex.	Ser. No.	Filed	Name	Class	Subcl.	
	09/073,118	05/05/1998	Gambale			
	09/159,834	09/24/1998	Cafferata			

U.S	. PATENT API	PLICATION DOCUMENTS
09/162,547	09/29/1998	Gambale
09/211,332	12/15/1998	Gambale et al.
09/299,795	04/26/1999	Ahern
09/328,808	06/09/1999	Ahern
09/368,119	08/04/1999	Tedeschi et al.
09/743,695	04/12/2001	Weiser et al.
09/743,726	04/12/2001	Gambale et al.
09/888,757	06/25/2001	Ahern et al.
09/990,644	11/21/2001	Gambale et al.
10/048,205	05/02/2002	Gambale
10/048,694	06/10/2002	Gambale et al.

			REIGN PA	TENT DOCUMENTS		
Ex.		Doc. No.	Date	Name	Class	Subcl.
	*	DE 19703482	01/1997	Dotter		
	*	DE 29619029	04/1997	Kletka		
	*	EP 0 490 459A1	10/1994	De La Caffiniere		
	*	EP 0 515 867 A2	12/1992	Jeevanandam		
	*	EP 0 714 640 A1	06/1996	Stack		
	*	EP 0 717 969A2	06/1996	Sepetka et al.		
	*	EP 0 732 089 A2	09/1996	Anderson et al.		
	*	EP 0 812 574 A2	12/1997	Mueller et al.		
	*	EP 0 830 873 A2	03/1998	Ogawa et al.		
	*	EP 0 853 921 A2	07/1998	Harman et al.		
	*	EP 0 953 320 A2	11/1999	Tuch		
	*	FR 1514319	01/1967	Zacouto		
	*	FR 2725615	10/1994	De la Caffiniere		
-	*	RU 2026640 C1	01/1995	Abstract of Russian		
				Patent		
	*	RU 2063179 C1	07/1996	Abstract of Russian		
				Patent		
	*	WO 89/01798	03/1989	Jacobsen		·
	*	WO 91/15254	10/1991	Zimmon		
	*	WO 94/05265	03/1994	Berde et al.		
	*	WO 94/27612	12/1994	French et al.		
	*	WO 96/20698	07/1996	Levy et al.		
	*	WO 97/42910	07/1997	Bruess et al.		
	*	WO 97/32551	09/1997	Hussein et al.		
	*	WO 97/38730	10/1997	Bertrand et al.		
	*	WO 97/44071	11/1997	Sudai		
	*	WO 97/45105	12/1997	Hunter et al.		
	*	WO 97/47253	12/1997	Fine		
	*	WO 98/05307	02/1998	Kaplan et al.		
	*	WO 98/08456	03/1998	Makower et al.		
	*	WO 98/16644	04/1998	Deisher et al.		
	*	WO 98/23228	06/1998	Burkoth et al.		
	*	WO 98/25533	06/1998	Hektner		

		FOREIGN PA	TENT DOCUMENTS	
*	WO 98/29148	07/1998	Yang et al.	
*	WO 98/32859	07/1998	Rosengart	
*	WO 98/46115	10/1998	Makower et al.	
*	WO 99/21510	05/1999	Evans	
*	WO 99/38459	08/1999	Wilk	
*	WO 99/53863	10/1999	Vanney et al.	

 ,	OTHER DOCUMENTS (including, Author, Title, Date, Pages, Etc.)
*	Abela et al., "Laser Revascularization: What Are Its Prospects?" Journal of
	Cardiovascular Medicine pp 977-984 (09/1983)
*	Abela et al., "Use of Laser Radiation to Recanalize Totally Obstructed Coronary
	Arteries" (Abstract) Journal American College Cardiology 1:691(1983)
*	Anabtawi et al., "Experimental Evaluation of Myocardial Tunnelization as a Method
	of Myocardial Revascularization" Journal of Thoracic and Cardiovascular Surgery
	58:638-646 (11/1969)
*	Dotter, "Transluminally-placed Coilspring Endarterial Tube Grafts: Long-term
 	Patency in Canine Popliteal Artery" <i>Investigative Radiology</i> pp 329-332 (9-10/1969)
*	Goldman et al., "Experimental Methods for Producing a Collateral Circulation to the
	Heart Directly from the Left Ventricle" Journals of Thoracic Surgery 31:364-374
	(03/1956)
*	Hardy et al., "Regional Myocardial Blood Flow and Cardiac Mechanics in Dog
	Hearts with CO₂ Laser-Induced Intramyocardial Revascularization" Basic Research
 	Cardiology 85:179-197 (1990).
*	Hershey et al., "Transmyocardial Puncture Revascularization" Geriatrics pp 101-108
	(03/1969)
*	Ingels, et al., "Measurement of Midwall Myocardial Dynamics in Intact Man by
	Radiography of Surgically Implanted Markers" Circulation 52:859-867 (11/1975)
*	Jevanandam et al., "Myocardial Revascularization by Laser-Induced Channels"
	Surgical Forum Vol. VL, American College of Surgeons 76 <sup>th</sup> Clinical Congress
	4:225-227 (10/1990)
*	Khazei et al., "Myocardial Canalization, A new Method of Myocardial
	Revascularization" The Annals of Thoracic Surgery 6:163-171 (08/1968)
*	Kuzela et al., "Experimental Evaluation of Direct Transventricular Revascularization"
	Journal of Thoracic Cardiovascular Surgery 57:770-773 (1969)
*	Lee et al., "Feasibility of Intravascular Laser Irradiation for In vivo Visualization and
	therapy of Cardiocirculatory Diseases" American Heart Journal 103:1076-1077
	(06/1982)
*	Lee et al., "Laser-Dissolution of Coronary Atherosclerotic Obstruction" American
 	Heart Journal 102:1074-1075 (12/1981)
*	Massimo, et al., "Myocardial Revascularization By a New Method of Carrying Blood
	Directly from the Left Ventricular Cavity into the Coronary Circulation" Journals of
	Thoracic Surgery 34:257-264 (08/1957)
*	Mirhoseini et al., "Revascularization of the Heart by Laser" Journal of Microsurgery
	2:253-260 (06/1981)
 *	Mirhoseini et al., "Clinical Report: Laser Myocardial Revascularization" Lasers in
	Surgery and Medicine 6:459-461 (1986)
*	Mirhoseini et al., "Myocardial Revascularization by Laser: A Clinical Report" Lasers
	in Surgery and Medicine 3:241-245 (1983)
*	Mirhoseini et al., "New Concepts in Revascularization of the Myocardium" The
	Annals of Thoracic Surgery, 45:415-420 (04/1988)

	OTHER DOCUMENTS (including, Author, Title, Date, Pages, Etc.)
*	Mirhoseini et al., "Transventricular Revascularization by Laser" Lasers in Surgery and Medicine 2:1987-1998 (1982)
*	Pifarre et al., "Myocardial Revascularization by Transmyocardial Acupuncture: A Physiologic Impossibility" <i>Journal of Thoracic and Cardiovascular Surgery</i> 58:424-429 (09/1969)
*	Sachinopoulou et al., "Invited Review Transmyocardial Revascularization" Lasers in Medical Science" 10:83-91 (09/1995)
*	Schumacher et al., "Induction of Neoangiogenesis in Ischemic Myocardium by Human Growth Factors, First Clinical Results of a New Treatment of Coronary Heart Disease" Circulation 97:645-650 (12/1997)
*	Sen et al., "Transmyocardial Acupuncture, A New Approach to Myocardial Revascularization" <i>Journal of Thoracic and Cardiovascular Surgery</i> 50:181-189 (08/1965)
*	Sen et al., "Further Studies in Multiple Transmyocardial Acupuncture as a Method of Myocardial Revascularization" Surgery 64:861-870 (11/1968)
*	Walter et al., "Treatment of Acute Myocardial Infarction by Transmural Blood Supply from the Ventricular Cavity" <i>Europ. Surg. Res.</i> 3:130-138 (1971)
*	Whittaker et al., "Transmural Channels Can Protect Ischemic Tissue, Assessment of Long-term Myocardial Response to Laser and Needle-Made Channels" Circulation 93:143-152 (01/1996)

Examiner:	Date considered

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. An \* indicates references that do not require a copy to be provided under 37 C.F.R. §1.98(d) because a copy was previously cited or submitted in a prior application, which is relied upon under 35 U.S.C. §120.